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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. SANDOZ INC., Defendant.	CASE NO. CV12 0446 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), state the following as their Complaint against Defendant Sandoz Inc.:

I.

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation with a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. TPC's business includes the research, development, and marketing of pharmaceutical products.

2. TPC is the owner of record and assignee of U.S. Patent No. 6,462,058 (the "'058 Patent"), U.S. Patent No. 6,664,276 (the "'276 Patent"), U.S. Patent No. 6,939,971 (the "'971 Patent"), U.S. Patent No. 7,285,668 (the "'668 Patent"), and U.S. Patent No. 7,790,755 (the "'755 Patent") (collectively, the "Asserted Patents").

3. Plaintiff Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc. ("TPNA"), is a Delaware corporation with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPNA's business includes the research, development, and marketing of pharmaceutical products. TPNA is the registered holder of approved New Drug Application No. 22-287. In addition, TPNA has the exclusive right to import dexlansoprazole delayed release capsules into the United States and sell those capsules to Takeda Pharmaceuticals LLC.

4. Plaintiff Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda LLC's business includes the purchase and sale of pharmaceutical products. Takeda LLC is an exclusive licensee of the Asserted Patents.

5. Plaintiff Takeda Pharmaceuticals America, Inc. ("TPA"), is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPA's business includes the purchase, sale, and marketing of pharmaceutical products. TPA has the exclusive right

to purchase dexlansoprazole delayed release capsules from Takeda LLC and sell those capsules to the public in the United States.

6. Plaintiffs are informed and believe, and thereupon allege, that Defendant Sandoz Inc. ("Sandoz") is a Colorado corporation with a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540.

7. Unless specifically stated otherwise, the acts complained of herein were committed by, on behalf of, and/or for the benefit of Sandoz.

II.

NATURE OF THE ACTION

8. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Sandoz with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' DEXILANT products.

9. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has been infringing, is infringing, or will infringe one or more claims of each of the Asserted Patents.

III.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Sandoz because Sandoz has purposefully availed itself of the privilege of doing business in the State of California by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of California, and/or by selling, directly or through its agents, pharmaceutical products in the State of California.

12. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in California and this district, including the sale of Sandoz's products in

California and this district. Sandoz's website states, "We develop, produce and market a portfolio of approximately 1 000 high-quality and cost-effective generic compounds, including complex biosimilars, an emerging field in which we are the pioneer and global leader."

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

IV.

INTRADISTRICT ASSIGNMENT

14. For purposes of intradistrict assignment pursuant to Civil Local Rules 3-2(c) and 3-5(b), this Intellectual Property Action is to be assigned on a district-wide basis.

V.

FACTUAL BACKGROUND

A. Asserted Patents

1. The '058 Patent

15. On October 8, 2002, U.S. Patent No. 6,462,058, titled "Benzimidazole Compound Crystal," was duly and legally issued to Takeda Chemical Industries, Ltd., as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. On June 29, 2004, Takeda Chemical Industries, Ltd., changed its name to Takeda Pharmaceutical Company Limited (i.e., TPC). The change of the name of the assignee of the '058 Patent to TPC was recorded in the United States Patent and Trademark Office ("PTO") on January 19, 2005. A true and correct copy of the '058 Patent is attached as Exhibit A to this Complaint.

16. The expiration date of the '058 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the Orange Book) is June 15, 2020.

2. The '276 Patent

17. On December 16, 2003, U.S. Patent No. 6,664,276, titled "Benzimidazole Compound Crystal," was duly and legally issued to Takeda Chemical Industries, Ltd., as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. On June 29, 2004, Takeda

Chemical Industries, Ltd., changed its name to Takeda Pharmaceutical Company Limited (i.e., TPC). The change of the name of the assignee of the '276 Patent to TPC was recorded in the PTO on January 19, 2005. A true and correct copy of the '276 Patent is attached as Exhibit B to this Complaint.

18. The expiration date of the '276 Patent listed in the Orange Book is June 15, 2020.

3. The '971 Patent

19. On September 6, 2005, U.S. Patent No. 6,939,971, titled "Benzimidazole Compound Crystal," was duly and legally issued to TPC, as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. A true and correct copy of the '971 Patent is attached as Exhibit C to this Complaint.

20. The expiration date of the '971 Patent listed in the Orange Book is June 15, 2020.

4. The '668 Patent

21. On October 23, 2007, U.S. Patent No. 7,285,668, titled "Process for the Crystallization of (R)- or (S)-Lansoprazole," was duly and legally issued to TPC, as assignee of named inventors Hideo Hashimoto and Tadashi Urai. A true and correct copy of the '668 Patent is attached as Exhibit D to this Complaint.

22. The expiration date of the '668 Patent listed in the Orange Book is June 15, 2020.

5. The '755 Patent

23. On September 7, 2010, U.S. Patent No. 7,790,755, titled "Controlled Release Preparation," was duly and legally issued to TPC, as assignee of named inventors Yohko Akiyama, Takashi Kurasawa, Hiroto Bando, and Naoki Nagahara. A true and correct copy of the '755 Patent is attached as Exhibit E to this Complaint.

24. The expiration date of the '755 Patent listed in the Orange Book is August 2, 2026.

B. <u>DEXILANT</u>

25. Plaintiff TPNA is the registered holder of approved New Drug Application No. 22-287 for the manufacture and sale of the drug dexlansoprazole, a proton pump inhibitor, for the treatment of all grades of erosive esophagitis, maintaining healing of esophagitis, and treating

heartburn associated with symptomatic non-erosive gastroesophageal reflux disease ("GERD"). Plaintiff TPA sells dexlansoprazole in the United States under the trade name DEXILANT, in 30 mg and 60 mg dosage forms. The 30 mg and 60 mg dosage forms of DEXILANT were approved by the FDA on January 30, 2009.[1]

26. Plaintiffs are informed and believe, and thereupon allege, that DEXILANT is the first and only acid reflux disease treatment specifically designed for the release of medicine in two stages over time. The key to this two-stage release is DEXILANT's Dual Delayed Release™ formulation ("DDR"). DDR combines two different types of granules in one pill. DEXILANT releases one dose of medicine within an hour of taking a pill. Then, around four to five hours after ingestion, DEXILANT releases a second dose of medicine.

27. The Asserted Patents are listed in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

C. Infringement by Sandoz

28. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has submitted ANDA No. 203-504 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market dexlansoprazole delayed release capsules in the 60 mg dosage form (the "Proposed Capsules") as a generic version of DEXILANT, prior to the expiration dates of the Asserted Patents.

29. On December 20, 2011, TPNA received a letter dated December 19, 2011 (the "Notice Letter") via overnight delivery from Sandoz addressed to TPC, TPNA, and others. This was the first Notice Letter that any of the Plaintiffs received related to ANDA No. 203-504.

30. On December 22, 2011, TPC received a copy of the Notice Letter via overnight delivery from Sandoz.

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[1] Plaintiffs originally marketed the drug dexlansoprazole under the proprietary name KAPIDEX. On March 4, 2010, the FDA announced that TPNA would start marketing KAPIDEX under the new name DEXILANT to avoid potential confusion with two other medications, CASODEX and KADIAN.

31. The Notice Letter stated that the ANDA included a Paragraph IV Certification that, in Sandoz's opinion, the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules.

32. Plaintiffs are informed and believe, and thereupon allege, that the ANDA does not provide any valid basis for concluding that the Asserted Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules.

33. Plaintiffs are informed and believe, and thereupon allege, that the submission of the ANDA to the FDA constitutes infringement of the Asserted Patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, or import of the Proposed Capsules would infringe the Asserted Patents under 35 U.S.C. § 271(a)–(c).

34. Plaintiffs commenced this action within 45 days of receiving the Notice Letter, as required by 21 U.S.C. § 355(j)(5)(B)(iii).

VI.

CLAIMS FOR RELIEF

COUNT I

(Patent Infringement of U.S. Patent No. 6,462,058)

35. Plaintiffs incorporate by reference and reallege paragraphs 1 through 34 above as though fully restated herein.

36. Pursuant to 35 U.S.C. § 271(e)(2), Sandoz's submission of ANDA No. 203-504 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '058 Patent.

37. Unless Sandoz is enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Sandoz's infringement of the '058 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT II

(Patent Infringement of U.S. Patent No. 6,664,276)

38. Plaintiffs incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Sandoz's submission of ANDA No. 203-504 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '276 Patent.

40. Unless Sandoz is enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Sandoz's infringement of the '276 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT III

(Patent Infringement of U.S. Patent No. 6,939,971)

41. Plaintiffs incorporate by reference and reallege paragraphs 1 through 40 above as though fully restated herein.

42. Pursuant to 35 U.S.C. § 271(e)(2), Sandoz's submission of ANDA No. 203-504 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '971 Patent.

43. Unless Sandoz is enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Sandoz's infringement of the '971 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(Patent Infringement of U.S. Patent No. 7,285,668)

44. Plaintiffs incorporate by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

45. Pursuant to 35 U.S.C. § 271(e)(2), Sandoz's submission of ANDA No. 203-504 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '668 Patent.

46. Unless Sandoz is enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Sandoz's infringement of the '668 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT V

(Patent Infringement of U.S. Patent No. 7,790,755)

47. Plaintiffs incorporate by reference and reallege paragraphs 1 through 46 above as though fully restated herein.

48. Pursuant to 35 U.S.C. § 271(e)(2), Sandoz's submission of ANDA No. 203-504 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '755 Patent.

49. Unless Sandoz is enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Sandoz's infringement of the '755 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(Declaratory Judgment as to U.S. Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,285,668, and 7,790,755)

50. Plaintiffs incorporate by reference and reallege paragraphs 1 through 49 above as though fully restated herein.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. Plaintiffs are informed and believe, and thereupon allege, that Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Proposed Capsules prior to patent expiry.

53. Plaintiffs are informed and believe, and thereupon allege, that Sandoz intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules upon receipt of final FDA approval of ANDA No. 203-504.

54. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Sandoz's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules would constitute infringement of the '058, '276, '971,'668, and '755 Patents.

55. Plaintiffs are informed and believe, and thereupon allege, that Sandoz's infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Proposed Capsules complained of herein will begin following FDA approval of ANDA No. 203-504.

56. Sandoz maintains, and Plaintiffs deny, that the Asserted Patents are invalid or unenforceable. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Sandoz regarding whether Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of the Proposed Capsules according to ANDA No. 203-504 will infringe one or more claims of the Asserted Patents. Plaintiffs thus are entitled to a declaration that the making, using, sale, offer for sale, and importation into the United States of the Proposed Capsules according to ANDA No. 203-504 infringe one or more claims of the Asserted Patents.

VII.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a declaration that Sandoz has infringed each of the Asserted Patents;

B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or importation by Sandoz of the Proposed Capsules would infringe each of the Asserted Patents;

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of the ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be no earlier than the expiration date of the last of the Asserted Patents, including any extensions or adjustments;

D. For an order preliminarily and permanently enjoining Sandoz and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns,

and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the Asserted Patents; and

E. For such other and further relief as this Court deems just and proper.

Respectfully Submitted,

DATED: January 27, 2012

MUNGER, TOLLES & OLSON LLP

By: _____
HEATHER E. TAKAHASHI

Attorneys for Plaintiffs
TAKEDA PHARMACEUTICAL CO., LTD.,
TAKEDA PHARMACEUTICALS U.S.A., INC.,
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